INDEPENDENT
INVESTIGATIONAL
REVIEW BOARD INC.
*Your Advocate for Clinical Research Participants*

**DATE:** April 18, 2006

**TO:** Scott P. Carroll, Ph.D.
Principal Investigator

**FROM:** Kim Lerner, Chairman or
Anita McSharry, Vice-Chairman
Independent Investigational Review Board, Inc.

**SUBJECT:** Approval Clinical Research Protocol dated: April 13, 2006

- Informed Consent Form (Ver. 4/18/06)
- MSDS for WV29-01, EU26-16, EU26-15
- California Experimental Subject's Bill of Rights
- Site Questionnaire

**PROTOCOL:** (EMD-004) Test of Personal Insect Repellents

The Independent Investigational Review Board, Inc. is an institutional review committee structured in compliance with the regulations of the Food and Drug Administration contained in the Code of Federal Regulations (2ICFR 50 and 56), Environmental Protection Agency (40 CFR Parts 9 and 26), and is in compliance with the International Conference of Harmonization (ICH) Good Clinical Practice (GCP) guidelines for IRB/IECs.

At the April 18, 2006 meeting, the Committee reviewed and unanimously approved the Research Protocol, the Investigator, Informed Consent Form, California Experimental Subject's Bill of Rights, and MSDS for the above noted research study. The Site Questionnaire was reviewed and accepted as submitted. The Committee recommended that minor changes be made to the Informed Consent Form. These recommendations have been incorporated into the approved Informed Consent Form identified as Version 4/18/06, and stamped "Approved 4/18/06". The Informed Consent Form contains all regulatory required consent elements.

The study has been approved for a one year period. At the end of this time, you are required to provide the Independent Investigational Review Board with a written progress report and completed Informed Consent Form for this research and obtain approval for continuing the research.

*phone 954-327-0778 • fax 954-327-5778 • 6738 West Sunrise Blvd., Suite 102 • Plantation, FL 33313 • info@iirb.com (email) • www.iirb.com*

Changes to the protocol or use of non-approved recruitment materials cannot be initiated without IIRB review and approval.

In the event of any serious adverse reactions, significant deviations from the protocol or problems in the research, written notice to the Independent Investigational Review Board is required. Please provide this reporting to the above-noted address so that appropriate follow-up will be initiated.

Thank you for your cooperation.

KL/AMS/ds/rr

# INFORMED CONSENT AUTHORIZATION TO PARTICIPATE AS A RESEARCH STUDY SUBJECT

**Title of Study:** (EMD-004) Test of Personal Insect Repellents

**Principal Investigator:** Scott P. Carroll, Ph.D.
Carroll-Loye Biological Research
711 Oak Ave
Davis, CA 95161

**Site of Investigation:** _____
_____
_____

**Sponsor:** EMD Chemicals, Inc.

**Participant's Name:** _____

You are being asked to participate in a research study. Your participation is voluntary. The information in this Informed Consent Form explains the study. You will receive a copy of this form, and you may take it home and think about it before making your decision. If you have any questions, or do not understand anything in this form, please ask the Principal Investigator to explain any words or information you do not clearly understand.

**Nature and Purpose**
Carroll-Loye Biological Research is conducting this research study in order to develop effective mosquito repellents.

The purpose of the study is to compare the repellent characteristics of the test materials in three different dosage forms with an industry standard as a positive control and no treatment as a negative control in the field with mosquitoes. The information gathered will be used to develop personal repellents for future commercial marketing.

Deep Woods Off!™ is an approved repellent that contains 20% DEET and will be used as the positive control.

The sponsor EMD Chemicals, Inc. has contracted Carroll-Loye Biological Research to conduct the study. Scott Carroll, Ph.D. of Carroll-Loye Biological Research is the Principal Investigator in charge of the study.



APPROVED BY
Independent IRB
Signature 4/18/06 Date

Initials: _____
Date: _____

**SUBJECT SELECTION**
You have been offered an opportunity to participate in this research study because you are a male or female and 18 years of age or older. If you are a female of child bearing potential you cannot be pregnant or breastfeeding.

Approximately 20 volunteers will be enrolled in this field research study.

**Study Duration**
This study will require one field site visit. A screening visit is required within 14 days of the field site visit.

**Study Procedures**
**Study Design**
You will be randomly (by chance) assigned to receive one of three investigational formulations (Lotion, Pump, and Aerosol), DEET and no treatment. A minimum of 6 subjects will receive one of the 3 test formulations and a minimum 1 subject will be assigned to the negative and positive control groups. For each material treatment you will have a pre-measured amount of test material applied to either your forearms or lower legs. You will not have a choice as to which group you are assigned. Neither you nor the principal investigator will know which of the study materials you are receiving; however, this information can be made available if medically necessary.

Screening Visit
Within 14 days of the study visit you will go to the laboratory and you will provide some basic information during a pre study visit with a researcher. If you agree to participate in the research study you will have your limb surface measured in order to calculate the dosage of test material you will need.

If you are a female, you will perform a pregnancy test using an Over the Counter (OTC) pregnancy kit in the morning prior to the start of the study. The results of your test will be verified a female technician that is qualified to make that determination. If you are pregnant, you will not be allowed to participate in the study.

Procedures
The study material will be applied by a Carroll-Loye technician. The skin surfaces to be treated are first cleansed with a fragrance free soap, rinsed with water/isopropanol (35%) solution, and then towel dried. The test products are applied to your forearms or lower legs with two fingertips as evenly as possible using a light rubbing motion.

You will enter into the test area within 10 minute of having treatments applied. You and a partner will continuously monitor your own exposed arms or legs and those of your partner for mosquitoes that land. If any mosquitoes land you will remove them immediately. Every five minutes a project leader will announce the



APPROVED BY
Independent IRB
Signature
4/18/06
Date

Initials: _____
Date: _____

beginning of the next five-minute interval. At each transition to a new interval you will record the number of mosquitoes that landed on your own treated skin on a data sheet.

**RESTRICTIONS**

- You must not be hypersensitive to mosquito bites
- Must not be sensitive to any of the test product ingredients
- Must not have used repellents within one week prior to the start of the study
- Must refrain from smoking or alcoholic beverages during the tests

**RISK/DISCOMFORTS**

A Material Safety Data Sheet (MSDS) will be provided for review prior to participation in the study. According to the MSDS, the proposed formulation is flammable. The material may cause skin, respiratory and eye irritation. If excessive inhalation it can cause respiratory irritation, headache and dizziness. If ingested it may cause temporary gastric distress.

If at anytime you feel ill, inform the Principal Investigator (or any of the study monitoring personnel), and you will be taken to receive medical attention. You may remove yourself for any reason from the study at anytime.

**Measures will be implemented to remove mosquitoes before they have an opportunity to bite. However you might get bitten by one or more mosquitoes.**

**PREGNANCY RISKS**

**The risks to the unborn are unknown and may be hazardous. If you are a woman of childbearing potential, it is important that you do participate in this study if you are, or if you think you may be pregnant.**

**UNKNOWN / UNFORESEEABLE RISKS**

In addition to the risks and discomforts listed above, there may be some unknown or infrequent and unforeseeable risks associated with the use of these formulations, including allergic reaction or interaction with a medication. You will be informed in a timely manner both verbally and in writing of any new information, findings or changes to the way the research will be performed that might influence his willingness to continue participation in this study.

**RESEARCH RELATED INJURIES**

If you are injured as a result of being in this study, treatment will be available from a health professional who is either on call or on site. Carroll-Loye Biological Research will cover the costs of such treatment. This does not cover any injuries resulting from normal work activities. For further information about this, you should call the office of Carroll-Loye Biological Research (530) 297-6080. Financial compensation for non-study related injuries for such things as lost



APPROVED BY
Independent IRB
Signature
4/18/06
Date

Initials: _____
Date: _____

wages, disability or discomfort due to injury is not available from Carroll-Loye Biological Research.

**You DO NOT waive your legal rights by signing this form.**

**RIGHT TO WITHDRAW OR REMOVAL FROM STUDY**
I understand that I am free to withdraw from this study at any time, and I agree to inform the Principal Investigator immediately if I intend to withdraw. It is understood that my decision to participate in this study or to withdraw from this study will not influence the availability of my future medical care and will involve no penalty or loss of benefits to which I am otherwise entitled. I may withdraw from this study at any time.

I agree that the Principal Investigator in charge of the study can remove me from this study without my consent for any reason, including, but not limited to:

a. His/her judgment that any condition or circumstance may jeopardize my welfare or the integrity of the study.
b. My failure to follow the instructions of the investigator(s).
c. If the study is stopped by the sponsor and/or Principal Investigator participating in the study prior to completion.

**TREATMENT ALTERNATIVE**
Since this study is not intended to provide any therapeutic or other health-related benefit, your alternative is to not participate in this study.

**BENEFITS**
There are no immediate benefits to you from your participation other than compensation for your participation.

**OFFER TO ANSWER ANY QUESTIONS ABOUT THIS STUDY**
If you have any questions or problems during this study, or if you think that you may have experienced a research-related injury, you should contact Scott Carroll of Carroll-Loye Biological Research at (530) 297-6080.

If you have any questions regarding your rights as a research volunteer, please contact Kim Lerner, Chairman of the Independent Investigational Review Board, Inc. at toll free (877) 888-IIRB (4472) during regular working hours. The Independent Investigational Review Board is a committee established for the purpose of protecting the rights of volunteers in a research study.

**COSTS AND REIMBURSEMENT**
There will be no costs to the research study participant from participating in this study



APPROVED BY
Independent IRB
Signature 4/18/06 Date

Initials: _____
Date: _____

For participation in the study, each research study participant will receive a cash payment of $15 per hour. Payment will be made at the end of the study or whenever the test subject withdraws from the study.

**CONFIDENTIALITY**

Representatives from the Sponsor, EMD Chemicals, Inc., the U.S. Environmental Protection Agency (EPA), the Food and Drug Administration (FDA) and the Independent Investigational Review Board, Inc. Review Board (an independent committee that reviewed the ethical aspects of this study to help protect the rights and welfare of study participants) may have access to all non-personal information collected in this study. Because of the need to release information to these parties absolute confidentiality cannot be guaranteed. Any information or reports published as a result of this study would not identify you by name, or any other personal identification.

**CONSENT AND SIGNATURES**

I have read, in a language that I understand well, and understand the information, which has been stated above. I have received satisfactory answers to all of the questions, which I have asked. I hereby voluntarily consent to take part in this study and to be a research study participant in this study. I authorize the use and disclosure of my medical information, and do **not** waive my legal rights by signing this Informed Consent Form. I shall receive a copy of the signed Informed Consent Authorization.

| | | |
|---|---|---|
| Date/Time | **Print** Subject Name | **Sign** Subject Name |
| Date/Time | Scott Carroll<br>**Print** Carroll-Loye Biological Resarch Representative | **Sign** Carroll-Loye Biological Research Representative |

Independent Investigational Review Board, Inc.
Approved: 4/18/06



APPROVED BY
Independent IRB
Signature
4/18/06
Date

Initials:

Date:

DEPARTMENT OF PESTICIDE REGULATION

# EXPERIMENTAL SUBJECT'S
# BILL OF RIGHTS

The rights below are the rights of every person who is asked to be in a research study. As an experimental subject I have the following rights:

1. To be told what the study is trying to find out,

2. To be told what will happen to me and whether any of the procedures, pesticides, or devices is different from what would be used in standard practice,

3. To be told about the frequent and/or important risks, side effects, or discomforts of the things that will happen to me for research purposes,

4. To be told if I can expect any benefit from participating, and, if so, what the benefit might be,

5. To be told the other choices I have and how they may be better or worse than being in the study,

6. To be allowed to ask any questions concerning the study both before agreeing to be involved and during the course of the study,

7. To be told what sort of medical treatment is available if any complications arise,

8. To refuse to participate at all or to change my mind about participation after the study is started. This decision will not affect my right to receive the care I would receive if I were not in the study,

9. To receive a copy of the signed and dated consent form,

10. To be free of pressure when considering whether I wish to agree to be in the study.

APPROVED BY
Independent IRB

Signature Date